

IN THE SPECIFICATION:

Please replace paragraph [0032] with the paragraph below:

[0032] In FIG. 1, in accordance with embodiments of the present invention, second elongate shaft 112 and third elongate shaft 120 may be made of various metallic and non-metallic hypodermic tubing materials. For example, metallic hypodermic tubing materials may include, but are not limited to, stainless steel and nickel-titanium alloy. Likewise, examples of non-metallic hypodermic tubing materials may include, but are not limited to, polycarbonate, poly(L-lactide) (PLLA), poly(D, L-lactide) (PLA), polyglycolide (PGA), poly(L-lactide-co-D, L-lactide) (PLLA/PLA), poly(L-lactide-co-glycolide) (PLLA/PGA), poly(D, L-lactide-co-glycolide) (PLA/PGA), poly(glycolide-co-trimethylene carbonate) (PGA/PTMC), polyhydroxybutyrate (PHBT), poly(phosphazene), polyD,L-lactide-co-caprolactone) (PLA/PCL), poly(glycolide-co-caprolactone) (PGA/PCL), polyanhydrides (PAN), poly(ortho esters), poly(phosphate ester) poly(amino acid), poly(hydroxy butyrate), polyacrylate, polyacrylamid polyacrylamine, poly(hydroxyethyl methacrylate), polyurethane, polysiloxane and their copolymers, polyethylene (PE), polypropylene (PP), polyvinylchloride (PVC), polytetrafluoroethylene (PTFE), polyether block amide (PEBA), polyamide and polyimide.

Please replace paragraph [0040] with the paragraph below:

[0040] In FIG. 3, in accordance with an embodiment of the present invention, outer surface 122 of needle 120 may be surrounded by and engaged with a needle depth control device 330, in the form of a stop collar, located proximate a proximal side of flange 312 of first elongate shaft 110. Needle depth control device 330 may include a plurality of longitudinal protrusions 332, for example, rails, with an inner surface 338 with a first thread 339 disposed thereon, a proximal end 335 and a distal end 336. Longitudinal protrusions 332 may be slidably disposed in an equal plurality of longitudinal grooves 342 disposed in

inner surface 115 of first elongate shaft 110 to permit movement along the longitudinal axis of catheter 100. Similarly, longitudinal grooves 342 prevent lateral movement of longitudinal protrusions 332. Longitudinal grooves 342 may extend for several inches from the proximal side of flange 312 toward proximal end 104 of catheter 100. A section of outer surface 122 of needle 120 may contain a second thread 352 that is the reciprocal of and may engage first thread 339 upon movement of needle 120 toward the distal end of catheter 100.

Although in the embodiment shown in FIG. 3 second thread 352 on needle 120 is shown to extend approximately the length of needle depth control device 330, other embodiments are possible in which second thread 352 may extend for longer and/or shorter distances. The extent of the engagement of first thread 339 and second thread 352 may be controlled from proximal end 124 of needle 120 by turning needle 120 to engage and/or disengage needle 120 with needle depth control device 330. Distal end 336 of needle depth control device 330 may function as a stop collar when it contacts the proximal side of flange 312 of first elongate shaft 110 upon needle 120 being urged toward distal end 103 of catheter 100. Therefore, an injection depth, that is, the distance needle 120 may be extended past distal end 324 of flared tip section 320, may be limited by setting needle depth control device 330 to a predetermined distance. For example, to set the injection depth to 5 mm past flared tip 328, needle depth controller 330 is set to travel only 5 mm before contacting the proximal side of flange 312. ~~Although, the~~ ~~Although the~~ predetermined distance may be selected at the proximal end of catheter 100, the distance is controlled at the distal end of catheter 100 by the needle depth control device 330.

Please replace paragraph [0067] with the paragraph below:

[0067] In accordance with the embodiment in FIG. 11, needle 1125 may include a dual lumen design. Specifically, a mandrel 1102, for example, a solid mandrel, and a second tube 1104 may both extend from the proximal end to the distal end of needle 1125. Likewise, needle 1125 may be filled with a material 1106 to hold

mandrel 1102 and second tube 1104 in substantially consistent positions relative to each other within needle 1125. Mandrel 1102 may provide the column strength needed to transmit the puncture force to needle tip 1128 from the proximal end of needle 1125. Mandrel 1102 may also help limit and/or prevent second tube 1104 and material 1106 from lengthening due to moisture or tensile effects. In this embodiment, mandrel 1102 may include a metallic material, for example, stainless steel or nickel-titanium alloy and second tube 1104 and material 1106 may each include expansion and contraction ~~resistant~~ resistant material(s), for example, a moisture resistant plastic or polymer.

Please replace paragraph [0081] with the paragraph below:

[0081] The term “therapeutic agent” as used herein may include one or more “therapeutic agents” or “drugs.” The terms “therapeutic agents” and “drugs” are used interchangeably herein and may include pharmaceutically active compounds, nucleic acids with and without carrier vectors such as lipids, compacting agents (such as histones), virus (such as adenovirus, ~~and~~ and ~~associated~~ ado~~associated~~ virus, retrovirus, lentivirus and α -virus), polymers, hyaluronic acid, proteins, cells and the like, with or without targeting sequences.

Please replace paragraph [0082] with the paragraph below:

[0082] Specific examples of therapeutic agents used in conjunction with the present invention may include, for example, pharmaceutically active compounds, proteins, cells, oligonucleotides, ribozymes, anti-sense oligonucleotides, DNA compacting agents, gene/vector systems (i.e., any vehicle that allows for the uptake and expression of nucleic acids), nucleic acids (including, for example, recombinant nucleic acids; naked DNA, cDNA, RNA; genomic DNA, cDNA or RNA in a non-infectious vector or in a viral vector and which further may have attached peptide targeting sequences; antisense nucleic acid (RNA or DNA); and DNA chimeras which include gene sequences and encoding for ferry proteins

such as membrane translocating sequences ("MTS") and herpes simplex virus-1 ("VP22")), and viral, liposomes, viral liposomes and cationic and anionic polymers and neutral polymers that are selected from a number of types depending on the desired application. Non-limiting examples of virus vectors or vectors derived from viral sources may include adenoviral vectors, herpes simplex vectors, papilloma vectors, adeno-associated vectors, retroviral vectors, and the like. Non-limiting examples of biologically active solutes may include anti-thrombogenic agents such as heparin, heparin derivatives, urokinase, and PPACK (dextrophenylalanine proline arginine chloromethylketone); antioxidants such as probucol and retinoic acid; angiogenic and anti-angiogenic agents and factors; anti-proliferative agents such as enoxaprin, angiopeptin, rapamycin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid; anti-inflammatory agents such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, acetyl salicylic acid, and mesalamine; calcium entry blockers such as verapamil, diltiazem and nifedipine; antineoplastic / antiproliferative / anti-mitotic agents such as paclitaxel, 5-fluorouracil, methotrexate, doxorubicin, daunorubicin, cyclosporine, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors; antimicrobials such as triclosan, cephalosporins, aminoglycosides, and nifurantoin nitrofurantoin; anesthetic agents such as lidocaine, bupivacaine, and ropivacaine; nitric oxide (NO) donors such as lisidomine linsidomine, molsidomine, L-arginine, NO-protein adducts, NO-carbohydrate adducts, polymeric or oligomeric NO adducts; anti-coagulants such as D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, enoxaparin, hirudin, Warafin Warfarin sodium, Dicumarol, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet factors; vascular cell growth promoters such as growth factors, growth factor receptor antagonists, transcriptional activators, and translational promoters; vascular cell growth inhibitors such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors,

translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin; cholesterol-lowering agents; vasodilating agents; agents which interfere with endogenous vascoactive mechanisms; survival genes which protect against cell death, such as anti-apoptotic Bcl-2 family factors and Akt kinase; and combinations thereof. Cells may be of human origin (autologous or allogenic) or may be from an animal source (xenogeneic), genetically engineered if desired to deliver proteins of interest at the insertion site. Any modifications are routinely made by one skilled in the art.

Please replace paragraph [0083] with the paragraph below:

[0083] Polynucleotide sequences useful in practice of the invention may include DNA or RNA sequences having a therapeutic effect after being taken up by a cell. Examples of therapeutic polynucleotides may include anti-sense DNA and RNA; DNA coding for an anti-sense RNA; or DNA coding for tRNA or rRNA to replace defective or deficient endogenous molecules. The polynucleotides may also code for therapeutic proteins or polypeptides. A polypeptide is understood to be any translation product of a polynucleotide regardless of size, and whether glycosylated or not. Therapeutic proteins and polypeptides may include as a primary example, those proteins or polypeptides that can compensate for defective or deficient species in an animal, or those that act through toxic effects to limit or remove harmful cells from the body. In addition, the polypeptides or proteins that may be injected, or whose DNA can be incorporated, may include without limitation, angiogenic factors and other molecules competent to induce angiogenesis, including acidic and basic fibroblast growth factors, vascular endothelial growth factor, hif-1, epidermal growth factor, transforming growth factor α and β , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α , hepatocyte growth factor and insulin-like insulin-like growth factor; growth factors; cell cycle inhibitors including CDK inhibitors;

anti-restenosis agents, including p15, p16, p18, p19, p21, p27, p53, p57, Rb, nFkB and E2F decoys, thymidine kinase ("TK") and combinations thereof and other agents useful for interfering with cell proliferation, including agents for treating malignancies; and combinations thereof. Still other useful factors, which may be provided as polypeptides or as DNA encoding these polypeptides, include monocyte chemoattractant protein ("MCP-1"), and the family of bone morphogenic proteins ("BMP's"). The known proteins may include BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 (Vgr-1), BMP-7 (OP-1), BMP-8, BMP-9, BMP-10, BMP-11, BMP-12, BMP-13, BMP-14, BMP-15, and BMP-16. Currently preferred BMP's are any of BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 and BMP-7. These dimeric proteins may be provided as homodimers, heterodimers, or combinations thereof, alone or together with other molecules. Alternatively or, in addition, molecules capable of inducing an upstream or downstream effect of a BMP may be provided. Such molecules may include any of the "hedgehog" proteins, or the DNA's encoding them.